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MERCK SHARP & DOHME CORP. and ISIS PHARMACEUTICALS, INC.

19 IN THE UNITED STATES DISTRICT COURT

20 FOR THE NORTHERN DISTRICT OF CALIFORNIA

21 SAN JOSE DIVISION

22 GILEAD SCIENCES, INC.,

23 Plaintiff and Counterdefendant,

24 v.

25 MERCK & CO., INC. (Defendant only), MERCK
26 SHARP & DOHME CORP., and ISIS
PHARMACEUTICALS, INC.

27 Defendants and Counterclaimants.

28 Case No. 5:13-cv-04057-BLF

**COUNTERCLAIMANTS' REPLY IN
SUPPORT OF MOTION FOR SUMMARY
JUDGMENT OF DIRECT, INDUCED AND
CONTRIBUTORY INFRINGEMENT**

Date: December 10, 2015
Time: 9:00 a.m.
Ctrm: 3, 5th Floor
Judge: Honorable Beth Labson Freeman

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1 Counterclaimants Merck Sharpe & Dohme Corp. and Isis Pharmaceuticals, Inc. (collectively,
 2 "Merck") hereby reply in support of their Motion for Summary Judgment of Direct, Induced and
 3 Contributory Infringement, ECF 167, and in response to the opposition filed by Gilead Sciences, Inc.
 4 ("Gilead"), ECF 175.

5 **INTRODUCTION**

6 Gilead, bereft of any legally cognizable argument, asks this Court to deny Merck's motion for
 7 summary judgment of infringement notwithstanding that Gilead has affirmatively conceded each and
 8 every element of direct, induced and contributory infringement. Withholding adjudication of invalidity
 9 would waste judicial resources and disserve the interests of justice. Gilead's contention that its challenge
 10 to validity of the patents in suit provides a basis to deny Merck's summary judgment motion rests upon a
 11 fundamental misreading of the only controlling authority Gilead relies upon: *Commil USA, LLC v. Cisco*
 12 *Systems, Inc.*, 135 S. Ct. 1920 (2015). The interpretation of *Commil* that Gilead urges on this Court is
 13 insupportable. Indeed, Gilead filed an amicus brief urging the Supreme Court to make precisely the
 14 ruling that it did, which is the exact opposite of the interpretation Gilead now advances. Any fair reading
 15 of *Commil* commands the conclusion that patent claims can be infringed whether or not they are valid.

16 Gilead finds itself in a situation of its own making. It is undisputed that Pharmasset scientists
 17 studied Merck's published patent application before they made sofosbuvir as a means of delivering
 18 Merck's patented compounds to the liver in order to treat Hepatitis C virus infection. Having *concededly*
 19 launched its sofosbuvir products with full knowledge that their use infringes the patents in suit, and
 20 having reaped billions of dollars in revenue from that launch, Gilead is in no position to argue now that it
 21 is unfair to hold Gilead to the summary judgment it invited.

22 **ARGUMENT**

23 **I. IN THE CONCEDED ABSENCE OF A FACTUAL DISPUTE, MERCK IS ENTITLED
 24 TO SUMMARY JUDGMENT OF INFRINGEMENT**

25 Under Rule 56, because Gilead has stipulated and conceded all the facts relevant to infringement,
 26 Merck is entitled to have infringement decided as a matter of law before trial. At its core, the purpose of
 27 Rule 56 is to conserve judicial, jury and party resources by avoiding a trial on factual issues where there
 28 is no dispute of material fact for the jury to resolve. Gilead's plea to withhold summary judgment

notwithstanding the absence of a material factual dispute would disserve the interests of justice by forcing Merck to prove up its infringement case before a jury when there is no factual dispute about infringement for the jury to decide.

A. Merck Is Entitled To Summary Judgment Because the Facts Establishing Direct, Induced and Contributory Infringement Are Undisputed

Rule 56 provides, in relevant part:

The court ***shall*** grant summary judgment if the movant shows that there is no genuine issue as to any material fact and the movant is entitled to judgment as a matter of law.

Fed. R. Civ. P. 56(a) (emphasis added). In 2007, Rule 56 was amended as part of the Style Project by changing “shall” to “should”, but in 2010 this change was reversed and the word “shall” was restored specifically “to express the *direction to grant summary judgment.*” Fed. R. Civ. P. 56(a) advisory committee’s note to 2010 amendment (emphasis added).

As the Supreme Court has explained:

Summary judgment procedure is properly regarded not as a disfavored procedural shortcut, but rather as an integral part of the Federal Rules as a whole, which are designed 'to secure the just, speedy and inexpensive determination of every action.

Celotex Corp. v. Catrett, 477 U.S. 317, 327 (1986). Since Gilead has conceded and stipulated to all the facts necessary to establish infringement, it would be manifestly unfair to Merck to deny summary judgment on that issue:

Rule 56 must be construed with due regard not only for the rights of persons asserting claims and defenses that are adequately based in fact to have those claims and defenses tried to a jury, but also for the rights of persons opposing such claims and defenses to demonstrate in the manner provided by the Rule, prior to trial, that the claims and defenses have no factual basis.

Id.; see also *Religious Tech. Center v. Netcom On-line Commc'n Servs., Inc.*, 907 F. Supp. 1361, 1366 (N.D. Cal. 1995) (entry of summary judgment is “mandated” against a party that, after adequate time for discovery, fails to make the necessary factual showing in response to a summary judgment motion).

1 The evidence of Professor Benet, Gilead's responses to Requests for Admission in this case, and
 2 the Stipulation between the parties establish each and every element of direct, induced and contributory
 3 infringement. *See* ECF 167; Opening Expert Report of Leslie Z. Benet (ECF 167-10) & Exh. K thereto
 4 (ECF 167-22); Gilead's responses to Requests for Admission (ECF 167-7 & 167-8); Joint Stipulation
 5 (ECF 154). Fact discovery in this case has closed; the parties have exchanged expert reports, and expert
 6 discovery on the issue of infringement has concluded. Merck's showing of infringement stands
 7 unrebuted by Gilead. The issue of infringement is ripe for summary adjudication.

8 **B. Gilead's Express Concession That There Is No Dispute About the Facts Establishing
 9 Infringement Further Supports The Grant of Summary Judgment**

10 In this case, not only are the facts establishing direct, induced and contributory infringement
 11 undisputed, but they are *conceded by the infringer to be undisputed*. This further supports the grant of
 12 summary judgment.

13 In response to Merck's showing of infringement, Gilead has not disputed any of the relevant
 14 facts. On the contrary, *Gilead has conceded the absence of any dispute* regarding the facts that establish
 15 direct, induced and contributory infringement. *See* Gilead Sciences, Inc.'s Responsive Moving Separate
 16 Statement in Opposition to Counterclaimant's Motion for Summary Judgment (ECF 175-1) at 2-15
 17 (*admitting* every fact set forth by Merck in its Separate Statement except for two preliminary facts with
 18 respect to each Patent-in-Suit that are not necessary to establish infringement); ECF 175 at 1 ("Gilead has
 19 *admitted* that the chemical structures of its blockbuster HCV treatment, Sofosbuvir®, are depicted by the
 20 Markush structures of the asserted claims"); *id.* at 1 n. 1 ("Gilead has *stipulated* . . . that Gilead had
 21 knowledge, as of the date of the launch of Sovaldi® and Harvoni®, that the use of Sovaldi® and
 22 Harvoni® in accordance with their respective labels resulted in use of the method defined by claims 1-2
 23 of Merck's '499 patent and in use of compounds defined by claims 1-3, 5, 7, and 9-11 of Merck's '712
 24 patent"); ECF 154.

25 Since all parties agree that there is no factual dispute as to infringement, all that remains is for the
 26 Court to give effect to Gilead's concessions by granting summary judgment of direct, induced and
 27 contributory infringement, as requested by Merck.

II. ACCOMMODATING GILEAD'S PLEA NOT TO BE ADJUDICATED AS AN INFRINGER WOULD WASTE JUDICIAL RESOURCES AND IS FORECLOSED BY CONTROLLING LAW

To “withhold judgment regarding infringement” as Gilead requests, ECF 175 at 2, would waste the resources of this Court and disserve the interests of justice. If summary judgment were not granted before trial, Merck would have to prove up its infringement case before the jury. There is no reason why the Court’s schedule should be burdened with the extra trial days that would be needed to try those issues to the jury in this case, since there is no factual dispute about infringement for the jury to resolve.

Gilead fares no better with its alternative plea that the adjudication of infringement be kept from the jury for fear that the jury might reject Gilead’s invalidity defense based on its status as an adjudged infringer. The question of infringement cannot be kept from the jury while the issue of validity is tried. Whereas Gilead’s challenge to validity is not relevant to deciding the issue of infringement (for the reasons set forth in Section III below), the converse is not true. Under controlling Federal Circuit law, evidence that Gilead infringes the Patents-in-Suit is directly relevant to rebut Gilead’s contention that the patents in suit are invalid for a purported lack of practical utility. *E.I. DuPont de Nemours & Co. v. Berkley & Co.*, 620 F.2d 1247, 1258-59 (8th Cir. 1980) (holding that the defendant “as an infringer, was thereby estopped from asserting that [the infringed] claims are invalid for lack of utility.”) (citation and internal quotation marks omitted); *Tapco Prods. Co. v. Van Mark Products Corp.*, 446 F.2d 420, 428 (6th Cir. 1971) (“one who appropriates the teachings of a patent may not deny the utility of the invention”); *accord Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 959 (Fed. Cir. 1983) (“Lack of utility cannot co-exist with infringement and commercial success.”) (citing and following *Du Pont* and *Tapco*).

In *Raytheon*, the district court held the asserted claims invalid for lack of utility but nevertheless reached the issue of infringement, holding that “if the claims were valid, Raytheon would be liable for having infringed them.” *Id.* at 955. The Federal Circuit specifically praised “[t]he wisdom of the trial court in deciding validity **and** infringement” in view of the “interrelation of those issues” *Id.* at 959 (emphasis added). Affirming the finding of infringement with respect to all but one of the claims, the Federal Circuit reversed the finding of invalidity with respect to the claims that were infringed, because “[a] correct finding of infringement of otherwise valid claims mandates as a matter of law a finding of utility under § 101.” *Id.* The reasoning and outcome of *Raytheon* shows that Gilead’s challenge to utility

1 does not eliminate the need to reach the issue of infringement, but rather requires that infringement be
 2 adjudicated.

3 Thus, the evidence of infringement – including Gilead’s stipulations to the facts that prove
 4 infringement – cannot be kept from the jury while it resolves the issue of validity. Gilead fears that the
 5 jury’s learning of Gilead’s infringement “would severely prejudice Gilead’s invalidity defenses.” ECF
 6 175 at 2. To the extent that evidence of Gilead’s status as an infringer would lead the jury to infer that
 7 Gilead’s invalidity defenses are without merit, that conclusion is ***mandated***, not forbidden.

8 Contrary to Gilead’s contention, the Federal Circuit has explained that judicial efficiency is best
 9 served by ***deciding the question of infringement*** even if the validity of the claims is challenged, and
 10 regardless of the ruling on validity:

11 Where, as here, the invalidity holdings are upheld, failure to resolve the
 12 infringement issue at trial is of limited effect. Had the invalidity
 13 determinations been reversed in relation to one or more of the three patents
 14 in suit, however, remand for further proceedings would have been required,
 15 placing at risk the potential for additional delay and expense, the possibility
 16 of recalling witnesses, a second appeal, and a consequent inefficient use of
 17 judicial resources. *Stratoflex v. Aeroquip Corp.*, 713 F.2d 1530, 218 USPQ
 18 871, 880 (Fed.Cir.1983). Further, evidence of infringement may bear on
 19 resolution of other issues. . . . ***Evidence of copying may defeat assertions***
 20 ***of nonenablement. Eibel Co. v. Paper Co.***, 261 U.S. 45, 65-55, 43 S. Ct.
 21 322, 329, 67 L.Ed. 523 (1923), or ***nonutility. See, E.I. DuPont de Nemours***
 22 & Co. v. Berkley & Co., Inc., 620 F.2d 1247, 1258-59, 205 USPQ 1, 9 (8th
 23 Cir. 1980).

24 ***The better practice is to decide both issues*** when both are
 25 presented at trial.

26 *Medtronic, Inc. v. Cardiac Pacemakers, Inc.*, 721 F.2d 1563, 1582-83 (Fed. Cir. 1983) (emphasis added).
 27 See also *Cardinal Chem. Co. v. Morton Int’l, Inc.*, 508 U.S. 83, 97 n. 19 (1993) (“[B]ecause this court is
 28 not a court of last resort, a holding of either invalidity or noninfringement by our court does not render
 the case moot, because it is not over.”) (quoting *Morton Int’l, Inc. v. Cardinal Chem. Co.*, 959 F.2d 948,
 953 (Fed. Cir. 1992) (Lourie, J., concurring)) (alteration in original).

29 Against this controlling Federal Circuit law, Gilead’s reliance on a single district court case from
 30 the Northern District of Illinois for the supposed efficiency of not adjudicating infringement is
 31 unavailing. See ECF 175 at 2 (citing *Recycling Scis. Int’l, Inc. v. Gencor Indus., Inc.*, Nos. 95-CV-736,
 32 95-CV-4422, 1999 WL 160060 (N.D. Ill. Mar. 12 1999)). Even if *Recycling* were controlling (which it is
 33 not), the facts of that case are readily distinguishable. In *Recycling*, the Court would have been required

to adjudicate the cross-motions filed by numerous parties for summary judgment of infringement and *non*-infringement. See Docket Entries 143-148, 151-152, 155-163, 165, 167-170, 173, 179-181 & 190-191 in *Recycling*.¹ Here, in stark contrast, Gilead has conceded the absence of a factual dispute regarding infringement, as set forth above, so that the Court need only give effect to Gilead’s concession. In *Recycling*, unlike here, proof of infringement was not relevant to rebut the infringer’s challenge to validity. Given the circumstances that (a) evidence of Gilead’s infringement is directly relevant to rebut Gilead’s invalidity argument based on purported lack of practical utility, and (b) the evidence of Gilead’s infringement is not only undisputed, but stipulated, Gilead’s citation to *Recycling* is entirely inapt.

III. GILEAD'S MISREADING OF *COMMIL* PROVIDES NO BASIS FOR RESISTING SUMMARY JUDGMENT

In *Commil*, the Supreme Court distinguished between infringement and validity as “separate issues under the Act” and explained: “When infringement is the question, the validity of the patent is not the question to be confronted.” *Commil*, 135 S. Ct. at 1928.

Gilead utterly misstates the holding in *Commil* as standing for the proposition that “an invalid patent cannot be infringed” ECF 175 at 1:4-5. Gilead’s tortured reading of *Commil* is demonstrated by comparing Gilead’s truncated quote with the full context in which the Supreme Court considered the language that Gilead quotes:

Gilead's Opposition Brief	Supreme Court's Opinion in <i>Commil</i>
<p>That an invalid patent cannot be infringed is “a simple truth, both as a matter of logic and semantics.” <i>Commil USA LLC v. Cisco Sys., Inc.</i>, 135 S. Ct. 1920, 1929 (2015).</p> <p>ECF 175 at 1:4-5.</p>	<p><i>To say that an invalid patent cannot be infringed, or that someone cannot be induced to infringe an invalid patent, is in one sense a simple truth, both as a matter of logic and semantics. But the questions courts must address when interpreting and implementing the statutory framework require a determination of the procedures and sequences that the parties must follow to prove the act of wrongful inducement and any related issues of patent validity. Validity and infringement are distinct issues, bearing different burdens, different presumptions, and different evidence.</i></p> <p><i>Commil</i>, 135 S. Ct. at 1929 (internal quotations omitted) (emphasis added to identify the words omitted by Gilead).</p>

¹ Second Declaration of Stephen S. Rabinowitz in Support of Counterclaimants' Motion for Summary Judgment of Infringement ("Rabinowitz II Decl."), Ex. 8.

1 In quoting the language of *Commil*, Gilead not only omits the critical phrase, “in one sense,” but also
 2 ignores the Supreme Court’s actual holding that: “Validity and infringement are distinct issues” *Id.*

3 Properly understood, *Commil* requires that this Court adjudicate the question of infringement
 4 notwithstanding that Gilead has challenged validity. Judges of this Court have rejected the meritless
 5 argument, made here by Gilead, that summary judgment of infringement cannot be granted when the
 6 accused infringer challenges the validity of the asserted claims.

7 As Judge Chen recently held:

8 In its opposition [to summary judgment of infringement], Sophos’s
 9 argument boils down to the contention that it cannot be said to infringe the
 10 ‘430 patent because it is invalid, and therefore summary judgment is not
 11 proper. *See Opp’n at 4 (“It is axiomatic that one cannot infringe an*
 12 *invalid patent.”)* (quoting *Richdel, Inc. v. Suspool Corp.*, 714 F.2d 1573,
 13 1580 (Fed. Cir. 1983)).

14 Sophos’s position lacks merit. **Fortinet is not asking this Court to make**
 15 **a liability determination on the ‘430 patent. Rather, Fortinet is just**
 16 **asking for partial summary judgment to dispose of the issue of**
 17 **infringement.** That does not bar Sophos from still arguing that the ‘430
 18 patent is invalid (which would preclude liability); it simply prevents
 19 Sophos from taking the position that it does not practice the invention
 20 claimed in the ‘430 patent. As Fortinet notes in its reply, it is not
 21 uncommon for courts to render partial summary judgment on infringement.
 22 *See, e.g., Apple, Inc. v. Samsung Elecs., Co., No. 12-CV-00630-LHK*, 2014
 23 U.S. Dist. LEXIS 8157, at *156 (N.D. Cal. Jan. 21, 2014) (granting
 24 Apple’s motion for summary judgment of infringement of the ‘172 patent).

25 *Fortinet, Inc. v. Sophos, Inc. et al.*, No. 13-CV-05831-EMC, Order Granting in Part and Denying in Part
 26 Plaintiff’s Motion for Summary Judgment (N.D. Cal. Oct. 28, 2015),² Slip Op. at 4-5 (granting summary
 27 judgment of infringement and noting that “this ruling does not bar Sophos from contesting the validity of
 28 the patent”); *accord Fujitsu Ltd. v. Belkin Int’l, Inc.*, No. 10-CV-03972-LHK, 2012 WL 4497966, at *14
 (N.D. Cal. Sept. 28, 2012) (granting summary judgment of claims 2, 4, 9, 14, 20 and 27 with respect to
 certain accused products); *id.* at *30, 31 (denying summary judgment of invalidity with respect to those
 same claims).

29 Judge Chen’s analysis is in accord with Federal Circuit precedent:

30 Though an invalid claim cannot give rise to liability for infringement,
 31 whether it is infringed is an entirely separate question capable of
 32 determination without regard to its validity.

33
 2 Rabinowitz II Decl., Ex. 9.

Medtronic, 721 F.2d at 1583.

It is inexplicable that Gilead so badly misstates the holding of *Commil*, particularly given that Gilead – represented by the same counsel as in this case – urged the Supreme Court to distinguish between infringement and validity as a matter of patent law. As Gilead stated in its amicus brief to the Supreme Court in *Commil*:

Noninfringement and invalidity are distinct concepts under the statute, as evidenced by the fact they are enumerated as separate defenses.

Brief of Amicus Curiae Gilead Sciences, Inc. in Support of Petitioner in *Commil USA, LLC v. Cisco Sys., Inc.*, No. 13-896.³ Contrary to Gilead’s newly-minted argument in this case, the Supreme Court’s opinion leaves no doubt that it recognized in *Commil* (as Gilead did when appearing as a friend of the court before the Supreme Court) “the long-accepted truth – perhaps the axiom – that infringement and invalidity are separate matters under patent law.” 135 S. Ct. at 1928.

For the reasons stated in *Commil*, *Medtronic* and *Fortinet*, Gilead’s challenge to validity is no basis for denying or delaying adjudication of Merck’s motion for summary judgment of infringement.

CONCLUSION

In view of the foregoing, and for the reasons set forth in Merck's prior submissions in support of the Motion for Summary Judgment, Merck respectfully requests that the Court grant its motion for summary judgment of direct, induced and contributory infringement of claims 1 and 2 of the '499 Patent and claims 1-3, 5, 7, and 9-11 of the '712 Patent.

³ Rabinowitz II Decl., Ex. 10.

1 Dated: November 19, 2015

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CERTIFICATE OF SERVICE

I certify that all counsel of record are being served on November 19, 2015 with a copy of this document via the Court's CM/ECF system.

/s/ Stephen S. Rabinowitz
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